REMARKS

I. Status of the Claims

Claims 1-25, and 29-33 are pending in this application and under examination. No claims are amended herein.

Applicant respectfully acknowledges the Office's withdrawal of the rejection to claims 21-23 and 29-30 under 35 U.S.C. § 112, second paragraph.

II. Statement Regarding Substance of the Interview under 37 C.F.R. § 1.133(b)

Applicant would like to thank Examiner Fisher for the telephonic interview on April 18, 2011, and for the Interview Summary dated April 20, 2011 ("Interview Summary"). As indicated in the Interview Summary, the Information Disclosure Statement submitted January 21, 2011, was discussed. In particular, the International Search Report (No. 18) was not initialed by the Examiner and JP 57091912 was crossed out. During the interview, Examiner Fisher indicated that the International Search Report was considered, but that JP 57091912 was not considered because an English abstract was not provided. Accordingly, an English abstract of JP 57091912 is attached herewith. Consideration of the foreign reference JP 57091912 is respectfully requested.

III. Rejection under 35 U.S.C. § 103

A. Zander and Duponchelle

In the Final Office Action, the Examiner maintains the rejection to claims 1-7, 11-14, 16-17, 20 and 24 under 35 U.S.C. § 103(a) as unpatentable over "Zander" (U.S. Patent No. 5,296,242, to Zander) in view of "Duponchelle" (U.S. Patent No. 6,309,673, to Duponchelle). (Final Office Action at page 3.) Applicant respectfully disagrees and

traverses this rejection for the reasons of record and for the following additional reasons.

In response to the Amendment dated January 21, 2011, the Examiner contends that "it would have been obvious . . . to manipulate the pH of the starting materials to achieve the desired final pH . . . [s]ince both Zander and Duponchelle are directed to the same type of compositions . . . ." (Final Office Action at 15-16.) The Examiner further states that "Applicants have not demonstrated the criticality of the pH of the initial solutions nor shown that they result in a materially different product that the final solution claimed and the final solution taught." (*Id.* at 16.)

The Examiner, however, fails to establish a *prima facie* case of obviousness. In particular, the Examiner has not shown why it would have been obvious, when Zander and Duponchelle are considered *as a whole*, for one of ordinary skill in the art to manipulate the pH of the alkaline solution to the claimed pH of 10.1 to 10.5. Rather, Zander and Duponchelle would have led one of ordinary skill in the art in an *entirely different direction* than the claimed alkaline solution pH and claimed medical solution overall. (*See* M.P.E.P. § 2141.02(VI) ("[a] prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention."))

The as-filed specification of the pending application teaches that it is the particular proportion of bicarbonate/carbonate in the first single solution that allows it to be in equilibrium with the partial pressure of carbon dioxide in the atmosphere. (As-filed Specification at page 3.) As a result, the bicarbonate/carbonate concentrations are stable and therefore, the pH of the alkaline solution and overall medical solution is also

stable. For instance, the medical solutions exemplified at page 12 of the as-filed specification contain approximately a 1:3 ratio of sodium bicarbonate to sodium carbonate; for Examples 5-8, there is almost a 1:6 ratio of sodium bicarbonate to sodium carbonate, etc. These examples, which contain a greater concentration of carbonate than bicarbonate in the first single solution (i.e., a greater starting amount of sodium carbonate than sodium bicarbonate added to the first single solution), lead to the conclusion that a "stable and biocompatible bicarbonate-based solution can be prepared, provided that the prepared solution comprises bicarbonate and carbonate in such proportions that the partial pressure of carbon dioxide . . . is of the same order of magnitude as the partial pressure of CO_2 in the atmosphere." (*Id.* at page 29.) In other words, in order for the first single solution to be in equilibrium with the partial pressure of carbon dioxide in the atmosphere, there must be a greater concentration of carbonate than bicarbonate in the first single solution.

Zander fails to recognize that the specific proportion of carbonate/bicarbonate is necessary to equilibrate with the CO_2 in the atmosphere in order to obtain a first single solution and an overall medical solution having a stable pH. To the contrary, Zander teaches away from having an alkaline solution wherein the concentration of carbonate is greater than the concentration of bicarbonate. For example, Zander specifically teaches a bicarbonate alkaline solution comprising 19.1 mmol alkali bicarbonate and 6.1 mmol alkali carbonate (i.e., a 3:1 ratio of alkali bicarbonate to alkali carbonate). (Zander at Abstract.) Therefore, the partial pressure of carbon dioxide in Zander's alkaline solution would *not* be expected to be in equilibrium with the partial pressure of atmospheric carbon dioxide. While Zander discloses that "DE-OS 3 514 346" teaches certain

concentrations of alkali bicarbonate and alkali carbonate such that the partial pressure of carbon dioxide does not change after contact with atmospheric air, Zander indicates that "no attempt is made in [DE-OS 3 514 346] to adjust physiological values of the acid-base status of said liquid." (Zander at col. 1, ll. 60-65.) Thus, Zander focuses on the particular pH of each of the two solutions and further, the amounts of bicarbonate/carbonate with respect to the amount of metabolizable organic acids "which is decisive for therapy." (Zander at col. 3, ll. 15-20.) Accordingly, Zander actually teaches away from the claimed alkaline solutions that have bicarbonate and carbonate in such proportions that the partial pressure of carbon dioxide is "of the same order of magnitude as a partial pressure of carbon dioxide in the atmosphere." (*See e.g.,* claim 1.) In view of Zander, one of ordinary skill would have been led away from the presently claimed medical solutions.

The Examiner states that Zander teaches that "the stability [of the compositions] over time is due to the partial pressure of the carbon dioxide," in discussing the Declaration under 1.132 submitted in the previous response. (Final Office Action at page 16.) The Examiner mischaracterizes the teachings of Zander. As discussed above, while Zander discusses that "DE-OS 3 514 346" teaches certain concentrations of alkali bicarbonate and alkali carbonate such that the partial pressure of carbon dioxide does not change after contact with atmospheric air, Zander diverges from this teaching and focuses instead on the particular pH of each of its solutions as well as the amounts of alkali carbonate/bicarbonate "in order to form the alkali salts of the added, metabolizable organic acids . . . ." Zander's teaching away is further evidenced by the fact that its bicarbonate alkaline solution contains more bicarbonate than carbonate and

thus, would not have a partial pressure of carbon dioxide similar to that of the atmosphere. Thus, the Examiner's contention that "Zander would be expected to have the same stability as instantly claimed," is baseless. Applicant respectfully points out that "[i]f the examiner is relying on personal knowledge to support the finding of what is known in the art, the examiner *must* provide an affidavit or declaration setting forth specific factual statements and explanation to support the finding. (*See* 37 CFR 1.104(d)(2)." M.P.E.P. § 2144.03(C) (emphasis added)). Applicant therefore submits that the above-quoted statement cannot be used to support a case of prima facie obviousness.

Duponchelle fails to remedy the deficiencies of Zander. Not only does Duponchelle teach away from Zander (*e.g.,* teaches that the high pH of the acidic solution of Zander is too high and Zander's organic acids "will enhance the formation of glucose degradation products, which in turn may damage the peritoneal membrane"), Duponchelle also teaches that it is "preferable to have all buffer available as bicarbonate." (Duponchelle at col. 3, ll. 42-58.) Thus, Duponchelle teaches away from Zander, and the claimed invention, which includes both bicarbonate and carbonate in a particular proportion as discussed above.

Accordingly, while the Examiner contends that Duponchelle teaches a "pH of the final solution being the same as Zander and instantly claimed," that is where any similarity ends. (Final Office Action at page 15.) Both Zander and Duponchelle teach away from the instant claims and furthermore, fail to teach the particular pH range of the claimed first single solution (i.e., 10.1 - 10.5). Therefore, neither reference teaches all of the elements of the claims. In addition, the conflicted teachings in the art fail to guide

one of ordinary skill in the art to the instantly claimed medical solutions. The law provides that a conclusion of obviousness based on the combination of prior art reference teachings requires that a person of ordinary skill in the art would have had a reasonable expectation of success in arriving at the claimed invention. This is reflected in the Guidelines:

> "The rationale to support a conclusion that the claim would have been obvious is that 'a person of ordinary skill in the art would have been motivated to combine the prior art to achieve the claimed invention and that there would have been a reasonable expectation of success.' If any of these findings cannot be made, then this rationale cannot be used to support a conclusion that the claim would have been obvious to one of ordinary skill in the art." Fed. Reg., Vol. 72, No. 195, at 57534 (reference omitted; emphasis added).

Here, the Examiner's *prima facie* case fails because there is *no* reasonable expectation of success in arriving at the claimed medical solutions. (*See* M.P.E.P. § 2143.02 (emphasis added)).

As demonstrated in the Declaration under 37 C.F.R. §1.132 of co-inventor Malin ERNEBRANT ("Declaration") submitted in the previous Response, the stability of a bicarbonate solution containing an approximate 1:6 ratio of carbonate to bicarbonate resulted in a stable pH over a period of 17 days. (Declaration at page 3, Table 4.) Thus, the Examiner's statement that "Applicants have not demonstrated the criticality of the pH of the initial solutions," is incorrect. It is the criticality of the proportion of carbonate/bicarbonate that allows the first single solution to be in equilibrium with the partial pressure of carbon dioxide in the atmosphere which subsequently allows the pH of the first single solution and overall medical solution to be stable over time. Evidence of unobvious or unexpected advantageous properties, such as superiority in a property

the claimed compound shares with the prior art, can rebut *prima facie* obviousness. (M.P.E.P. § 716.02(a)(II)).

Moreover, a person of ordinary skill in the art could not have predicted the improved properties of the claimed compositions, nor would not have had a reasonable expectation of success in arriving at the claimed medical solutions. In contrast with the currently pending claims, both Zander and Duponchelle teach away from having an alkaline solution comprising bicarbonate and carbonate in such proportions that a partial pressure of carbon dioxide in the first single solution is of the same order of magnitude as a partial pressure of carbon dioxide in the atmosphere. (*See e.g.,* claim 1.) Considering Zander and Duponchelle as a whole, a person of ordinary skill in the art could not have predicted that a composition comprising a specific proportion of carbonate/bicarbonate, as recited in the currently pending claims, would result in medical solutions that are stable over time. It is well established that an invention cannot be obvious if it yields unpredictable results. (*See* M.P.E.P. § 2143 and *2010 KSR Guidelines Update,* 75 Fed. Reg. 53647, 53653 (Sept. 1, 2010) ("a proper rejection based on the rationale that the claimed invention is a combination of prior art elements also includes a finding that the results flowing from the combination would have been predictable to a person or ordinary skill in the art.") 75 Fed. Reg. at 53647.)

Thus, because of the demonstrated unpredictability in the art, there is no case of *prima facie* obviousness. Applicant respectfully requests withdrawal of this rejection.

B. Zander, Duponchelle and Linden

In the Office Action, the Examiner maintains the rejection of claims 8-10, 15, 18-19, 21-23, 25 and 29-33 under 35 U.S.C. § 103(a) as unpatentable over Zander in view

of Duponchelle and further in view of "Linden" (International Patent Application No. WO 01/89478 to Linden et al.). (Final Office Action at page 10.) The Examiner concedes that Zander fails to teach "the addition of a third or fourth single solution," and "does not specify that the sterilization is heat sterilization at a temperature of at least 100°C," and relies on Linden to remedy these deficiencies. (*See id.*) Applicant respectfully disagrees and traverses this rejection.

Claims 8-10, 15, 18-19, 21-23, 25 and 29-33 are ultimately dependent from claim 1 and therefore encompass all the elements recited in claim 1. The shortcomings of Zander and Duponchelle and their failure to render the instant invention obvious have already been discussed above. Linden fails to overcome these shortcomings. Rather, Linden merely exemplifies multi-compartmental containers that may include bicarbonate with no indication as to the pH of that solution. (Linden at Examples 1-5.) Nowhere does Linden teach or suggest a particular proportion of carbonate/bicarbonate in its medical solutions, and fails to teach any solution containing any carbonate at all.

Accordingly, because Linden does not remedy the shortcomings of Zander and Duponchelle, the proposed combination fails to meet the limitations of the instant claims. Accordingly, Applicant respectfully requests that this rejection be withdrawn.

IV. Double Patenting Rejection

The Examiner maintains the rejection to claims 1-7, 11-14, 16-17, 20 and 24 on the grounds of provisional obviousness-type double patenting as unpatentable over claims 5-11, 14-17, 20 and 21 of U.S. Application No. 11/658,001 ("the '001 application"). (Final Office Action at page 18.) As discussed in the previous response,

Applicant respectfully requests that the Examiner hold the rejection in abeyance until allowable subject matter has been identified in the present application.

V. Conclusion

In view of the foregoing remarks, Applicant respectfully requests reconsideration of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: May 18, 2011

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Attachment: English Abstract of JP 57091912